

# Notice of Allowability

## Application No.

10/524,977

## Examiner

KRISTIN BIANCHI

## Applicant(s)

BIRD ET AL.

## Art Unit

1626

### - The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07/29/2008.
2. ☒ The allowed claim(s) is/are 11,13,14 and 16-29.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 07/29/2008
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 09/17/2008
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

**DETAILED ACTION**

Claims 11, 13, 14, and 16-29 are pending in the instant application. Claim 15 is cancelled by Examiner's Amendment. Claims 11, 13, 14, and 16-29 are allowed.

***Response to Amendment***

The amendment to the claims filed on July 29, 2008 has been considered and entered into the application. The grounds of rejection set forth in the office action dated April 29, 2008 are moot in view of Applicant's amendment. Therefore, the 35 USC 112 1st paragraph rejection is withdrawn.

In view of the allowance of the compound and pharmaceutical formulation claims (i.e. 11, 13 and 17-29), claims 14 and 16 have been rejoined.

**EXAMINER'S AMENDMENT**

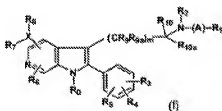
An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

This application has been amended as follows: claim 15 is cancelled. In claim 14, replace "pro-drug or solvate thereof" (lines 2 and 3) with "or in-vivo hydrolyzable ester thereof". The resulting claim should read "... a compound, or salt, or in-vivo hydrolyzable ester thereof...". In claim 16 (last line), replace "pro-drug or solvate" with "or in-vivo hydrolyzable ester". The resulting claim should read "... forming a salt, or in-vivo hydrolyzable ester."

**REASONS FOR ALLOWANCE**

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The following is an examiner's reasons for allowance. The instantly claimed compounds, formulations, method of making the compounds and method of using the compounds are novel and non-obvious over the prior art because of the structural limitations of the compounds wherein the core ring structure of the compounds is a pyrazole ring and the M variable is  $-(CH_2)-O-$ . The closest prior art is WO 00/53602 which discloses compounds which are useful as antagonists of GnRH, such as compounds with the following formula (i.e. claim 1)



wherein X is N, O, S(O)<sub>n</sub>, C(O), (C(R<sub>11</sub>R<sub>12</sub>)<sub>p</sub>), a single bond to R<sub>8</sub>, C2-C6 alkenyl, substituted C2-C6 alkenyl, C2-C6 alkynyl, or substituted C2-C6 alkynyl.

The compounds disclosed in WO 00/53602 do not have a pyrazole ring as their core ring structure and X is not  $-(CH_2)-O-$ . Therefore, the compounds of WO 00/53602 are not within the scope of the compounds of the instant claims nor are they obvious variants since the compounds disclosed in WO 00/53602 have different properties than the compounds of the instant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

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preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626

Kristin Bianchi  
Examiner

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